General

Guideline Title

ACR Appropriateness Criteria® radiologic management of inferior vena cava filters.

Bibliographic Source(s)

Kinney TB, Aryafar H, Ray CE Jr, Lorenz JM, Burke CT, Darcy MD, Fidelman N, Gervais DA, Hohenwalter EJ, Kapoor BS, Kolbeck KJ, Kouri BE, Mansour MA, Nair AV, Rochon PJ, Shaw CM, Expert Panel on Interventional Radiology. ACR Appropriateness CriteriaÂ® radiologic management of inferior vena cava filters. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 10 p. [69 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Kinney TB, Panko JE, Funaki BS, Ray CE Jr, Brown DB, Gemery JM, Kostelic JK, Lorenz JM, Mansour MA, Millward SF, Nemcek AA Jr, Owens CA, Reinhart RD, Silberzweig JE, Vatakencherry G, Expert Panel on Interventional Radiology. ACR Appropriateness Criteria® radiologic management of inferior vena cava filters. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 8 p.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Radiologic Management of Inferior Vena Cava (IVC) Filters

Variant 1: Acute pulmonary embolism with negative lower-extremity Doppler ultrasound.

Treatment/Procedure	Rating	Comments
Anticoagulation	9	
Permanent IVC filter	4	
Retrievable IVC filter	5	
Observation/conservative management	1	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Acute pulmonary embolism and/or iliofemoral deep vein thrombosis.

Treatment/Procedure	Rating	Comments
Anticoagulation	9	
Permanent IVC filter	5	
Retrievable IVC filter	6	
Observation/conservative management	1	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Symptomatic chronic pulmonary embolism.

Treatment/Procedure	Rating	Comments
Anticoagulation	9	
Permanent IVC filter	5	Depends strongly on the clinical factors such as lifelong risk, age, etc.
Retrievable IVC filter	5	
Pulmonary thromboendarterectomy	7	Clinical presentation (e.g., hemodynamic instability and right-sided heart failure) and anatomic factors are important considerations. Should be performed at center of excellence.
Observation/conservative management	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: Calf deep vein thrombosis.

Treatment/Procedure	Rating	Comments
Anticoagulation	7	Particularly in high-risk patients or if there is evidence of propagation.
Permanent IVC filter	2	
Retrievable IVC filter	3	If neither anticoagulation nor observation is possible or if there is evidence of propagation, this may be an option.
Observation/conservative management	6	For patients who have a contraindication to anticoagulation.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 5: Prophylactic IVC filter placement in high-risk patient without documented deep vein thrombosis/pulmonary embolism.

Treatment/Procedure	Rating	Comments
Anticoagulation	8	This assumes the patient is a candidate for anticoagulation.
Permanent IVC filter	2	
Retrievable IVC filter	5	
Observation/conservative management	5	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Treatment/Procedure	Rating	Comments
devices		
Surveillance US for deep vein thrombosis	4	Usually not necessary unless the patient becomes symptomatic.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 6: Phlegmasia cerulea dolens undergoing endovascular treatment.

Treatment/Procedure	Rating	Comments
Anticoagulation	9	
Permanent IVC filter	4	If patient has lifelong risk and cannot be anticoagulated.
Retrievable IVC filter	5	
Observation/conservative management	1	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 7: Upper-extremity deep vein thrombosis.

Treatment/Procedure	Rating	Comments
Anticoagulation	8	
Observation/conservative management	2	
Permanent SVC filter	3	
Retrievable SVC filter	5	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 8: Free-floating iliofemoral thrombus.

Treatment/Procedure	Rating	Comments
Anticoagulation	9	
Permanent IVC filter	6	Depends strongly on the clinical factors such as lifelong risk, age, etc.
Retrievable IVC filter	7	
Observation/conservative management	1	
Endovascular therapy	5	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 9: Retrieval of a filter placed for prophylaxis.

Treatment/Procedure	Rating	Comments
Automatically schedule for retrieval consultation at time of placement	9	
Clinic visit prior to retrieval	8	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Treatment/Procedure	Rating	Comments
Duplex of the lower extremities prior to retrieval	6	Depends on clinical presentation and new symptoms in examination interval.
CT venogram prior to retrieval	2	
KUB prior to retrieval	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 10: Retrieval of a filter placed for deep vein thrombosis/pulmonary embolism. Patient is now anticoagulated.

Treatment/Procedure	Rating	Comments
Retrieve filter with patient anticoagulated	8	
Clinic visit prior to retrieval	8	
Duplex of the lower extremities prior to retrieval	7	To check for propagation
CT venogram prior to retrieval	2	
KUB prior to retrieval	2	
Reverse anticoagulation prior to retrieval	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 11: Failed first retrieval attempt.

Treatment/Procedure	Rating	Comments
Consider the filter permanent with scheduled follow-up (imaging, clinic visit, operator choice)	5	
Consider the filter permanent without any follow-up	4	
Consider the filter permanent with lifelong anticoagulation	5	
Re-attempt retrieval with more aggressive measures	8	Consider referral to a center of excellence.
Refer for surgical evaluation for surgical retrieval	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

Pulmonary embolus (PE) and deep venous thrombosis (DVT) represent the clinical spectrum of venous thromboembolism (VTE), which remains a major cause of morbidity and mortality in hospitalized patients. VTE occurs spontaneously or as a common complication during and after hospitalization for acute medical or surgical illness. PE accounts for 5% to 10% of deaths in hospitalized patients and is the most common preventable cause of in-hospital death. Recent studies have emphasized that a significant number of medicine and surgery patients are not receiving adequate prophylaxis against VTE. More than 50% are at risk of VTE, and only half of those patients are receiving prophylaxis.

The primary prophylaxis and therapy for VTE are pharmacologic, including intravenous (IV) heparin, oral warfarin, or subcutaneous low-dose

heparin (LDH) or low-molecular-weight heparin (LMWH). Newer commercially available oral anticoagulation pharmacologic agents such as dabigatran are also gaining popularity. This agent does not require frequent hematologic tests to assess anticoagulation effect, and it has been shown to be as effective as warfarin in clinical trials for atrial fibrillation (Randomized Evaluation of Long-Term Anticoagulation Therapy [RE-LY] trial). Lower-extremity graduated compression stockings (GCS) and intermittent pneumatic compression (IPC) devices have been found to be effective as well. Surveillance ultrasound studies in lieu of anticoagulation have also been proposed.

Vena cava filters do not prevent or treat DVT. The sole function of inferior vena cava (IVC) filters is prevention of clinically significant and potentially life-threatening PE by preventing the passage of emboli into the pulmonary arterial circulation by trapping the embolus as it passes from the iliofemoral venous system through the IVC. They are placed percutaneously with relatively low risk to even severely ill patients.

Permanent IVC filters have been present for over 35 years, and studies show that the use of IVC filters has dramatically increased in the past 20 years. Despite this fact, there is a striking lack of rigorously performed clinical studies. The vast majority of the literature includes retrospective nonrandomized case series. Of 586 studies evaluated in a recent review, two-thirds were retrospective, and the heterogeneous study design of the few large prospective series precludes relevant comparison and analysis.

Filters were initially intended in the small group of patients who had VTE and a contraindication to anticoagulation, a complication of anticoagulation, inability to achieve adequate anticoagulation, or recurrent embolus despite anticoagulation.

The indications have been expanded by many authors to include a substantial proportion of patients with high risk of developing VTE but no evidence of it. The availability of retrievable/optional filter designs extends the clinical utility of filters. Proposed indications now include prophylactic use in patients with major trauma; in those who will undergo hip or knee replacement; in patients with compromised cardiopulmonary reserve such as cor pulmonale or pulmonary hypertension; in pregnant women with DVT; in burn patients; in patients undergoing thrombectomy, embolectomy, or thrombolysis; and patients with free-floating iliofemoral thrombus. Additionally, new indications that have been proposed lack significant data to support their use, such as prophylactic filter use for patients undergoing bariatric surgery.

Pulmonary Embolus with a Contraindication to Anticoagulation

There are certain absolute contraindications to anticoagulation in which filters are used to prevent PE. These include unsecured intracranial aneurysm after subarachnoid hemorrhage, acute intracerebral hemorrhage, or hematomyelia and current or recent major gastrointestinal hemorrhage or lesions at high risk of bleeding (e.g., esophageal varices). Relative contraindications include recent (within two weeks) major surgery, major trauma including cardiopulmonary resuscitation (CPR) or deep biopsy, uncontrolled hypertension, renal or hepatic disease, current guaiac-positive stools, and known bleeding diatheses. Neither stable peptic ulcer disease with no history of bleeding nor a history of guaiac-positive stools is a contraindication to anticoagulation. Anticoagulation is safe in most trauma and neurosurgical patients after the first or second postoperative week and in most stroke patients without hemorrhage. Patients with spinal cord injury without hematomyelia may still be considered for anticoagulation.

Major Complication of Anticoagulation

Major bleeding is the most significant complication of anticoagulation. It is defined as intracranial or retroperitoneal bleeding or bleeding that requires hospitalization or transfusion while the patient is on therapeutic levels of anticoagulants. When anticoagulation therapy for VTE must be stopped because of major bleeding, placement of an IVC filter should be considered. Heparin-induced thrombocytopenia — defined as platelet count below 50,000/μL, with or without arterial thrombosis — is also considered to be a complication of heparin therapy, and placement of an IVC filter should be considered after heparin is discontinued.

Inability to Adequately Anticoagulate

Progression or Recurrence of VTE despite Adequate Anticoagulation

Although VTE can progress during adequate anticoagulation, it is unusual and therefore it is critical to fully evaluate whether therapeutic levels have been consistently achieved. Raising the target international normalized ratio (INR) is preferable to placing a filter in the setting of inadequate anticoagulation. Hypercoagulable states such as antiphospholipid antibody or Trousseau's syndrome must be excluded prior to filter placement in order to avoid significant morbidity.

Patient Factors Affecting Anticoagulation

Elderly patients and patients who are unable to reliably comply with an anticoagulation regimen or have a history of falls are at increased risk of hemorrhage and complication, and filters have been used in these patients. Other factors that may affect anticoagulation status can include vitamin K-rich diets or other concurrent medications. Discomfort from frequent blood draws and/or self-injections may also cause patient compliance issues with currently available medications.

Pulmonary Thromboendarterectomy

Patients (3.8% or more) who experience initial symptomatic PE go on to chronic thromboembolic pulmonary hypertension (CTEPH). Permanent filters are routinely placed in these patients prior to thromboendarterectomy, and these patients are given lifelong anticoagulation as well.

Patients with Poor Cardiopulmonary Reserve

Among patients at high risk for death or severe morbidity from PE are those who have severe pulmonary hypertension and a history of PE. There are no data to support the use of prophylactic filters in this setting. When a patient has had multiple prior episodes of VTE and any additional embolization might result in severe morbidity or mortality, a filter may be indicated. Similarly, in a patient who has had cardiovascular collapse as the result of a PE and/or who has undergone pulmonary thrombolysis/embolectomy, the use of a filter may be warranted given the potential effects of re-embolization.

Free-floating Iliofemoral Thrombus

There has been much speculation about PE risk due to free-floating iliofemoral or IVC thrombus. A prospective study demonstrated no increased risk of PE. Although no study has demonstrated improved outcomes with IVC filters in addition to or in place of anticoagulation, this condition is still considered a relative indication in many consensus statements.

Prior to Thrombolysis

In the setting of proximal DVT, catheter-directed thrombolysis appears to result in fewer PEs than systemic thrombolysis. Filters are sometimes used but have not been shown to be more effective than thrombolysis alone. Retrievable filters may be a viable option in this situation.

Cancer Patients

Although cancer has been considered a contraindication to IVC filters in some instances, it is a prothrombotic state and independent risk factor for VTE. Filters have been recommended, but pharmacologic approaches such as LMWH are preferred over filters or oral anticoagulation in cancer patients.

Pregnancy

Pregnancy produces a hypercoagulable state, and VTE complicates 0.5% to 1% of pregnancies. Anticoagulation with heparin products is the mainstay of treatment, while warfarin is contraindicated due to teratogenicity. Filters are indicated in selected patients with contraindications to anticoagulation, progression of VTE while anticoagulated, and inability to tolerate a subsequent PE.

Patients without Venous Thromboembolic Disease

Prophylaxis in High-risk Trauma and Spinal Cord Injury Patients

Patients recovering from trauma, especially spinal cord injury patients, have the highest risk of VTE of all hospitalized patients. There is great controversy regarding the use of IVC filters in trauma patients, with some authors believing that there is no benefit to filters in trauma patients and that as soon as hemostasis is achieved (within 36 hours in most patients), pharmacologic prophylaxis should begin. Others believe that filters are safe and effective, though prospective randomized trials are severely lacking in this area.

Prophylaxis in High-risk Surgery Patients

Patients undergoing orthopedic procedures such as total knee and total hip arthroplasty are at high risk for VTE. Although retrievable filters are sometimes used in the perioperative period, pharmacologic therapies are safe and effective once the immediate risk of hemorrhage is past.

Prophylaxis in Burn Patients

Filter use in burn patients was found to be safe in a small series but is not an established indication for filter placement.

Prophylaxis in Bariatric Surgery Patients

PE is a leading cause of perioperative death in bariatric patients due to their many comorbidities. However, there is little evidence to support routine use of filters in place of adequate prophylaxis, such as anticoagulation.

Other Clinical Conditions

Patients with chronic obstructive pulmonary disease (COPD), pediatric patients, and organ transplant recipients have also been proposed as

potential recipients of IVC filters. However, none of these conditions preclude anticoagulation, and filters are suggested only after the accepted indications are met.

Septic Emboli

The proposed use of IVC filters in the patients with septic emboli is based on a single animal study and, given the risks of filter infection, is not recommended. Candida infection of filters has also been reported. Retrievable filters, if they become infected, can be removed.

Filters

Permanent and Retrievable Filter Designs

Permanent and retrievable filter designs are available. There are much more robust data on permanent filter designs, starting with the Greenfield in 1973 and including over 9,500 filter placements. To date, only 1,000 placements of retrievable designs are described in case series. Six permanent options currently available include the Gianturco-Roehm Bird's Nest, titanium and stainless steel Greenfield, Simon Nitinol, Vena Tech, and Trap Ease filters.

Retrievable designs were originally approved in 2003 and have recommended dwell times from 10 to 100 days. Six designs available in the United States include the Opt Ease, Gunther Tulip, Celect, Recovery, G2, and now the Option. Although retrieval is associated with relatively low complication rates, in one prospective observational study, longer dwell times decreased the rate of successful retrieval from 100% to 50%. Thrombus in a retrievable filter may prevent removal until a period of anticoagulation is possible.

Superior Vena Cava Filter Placement

Filter placement in the superior vena cava (SVC) is considered for patients with upper-extremity DVT. The decision is complicated by the short length of the available SVC and the associated increased risk of problematic migration or thrombosis. In addition, no filter is specifically designed for the SVC, and such use is considered off-label.

Temporary Inferior Vena Cava Filters (Externally Anchored)

Temporary filter designs in which the filter is anchored externally risk infection and have waned in popularity, given more appealing retrievable alternatives. Currently, there are no U.S. Food and Drug Administration (FDA)-approved IVC filters of this type in the United States.

Effectiveness

There has been only one randomized clinical trial on caval filters, the PREPIC study. In this study, 400 patients with iliofemoral DVT at high risk for PE were anticoagulated and assigned to either receive a permanent filter or not. Patients in both groups were checked for PE at 2 days and again at 8 to 12 days by ventilation-perfusion scan. Patients receiving filters had fewer PEs initially (as well as at 2- and 8-year follow-up periods), but over 2 years experienced more frequent DVT and no decrease in mortality. It is important to note that the PREPIC patients were all anticoagulated, while a typical patient receiving an IVC filter has a contraindication to anticoagulation. Therefore, the population of this study is not representative of patients in whom filters are routinely placed.

A single large population-based observational study involving nearly 75,000 patients in California showed that, in patients with prior VTE, those with filters were readmitted to the hospital for PE as often as those without filters. Among patients who had presented with initial PE, a filter was associated with double the relative risk of DVT. Time to recurrent PE was similar, and among those who had never been hospitalized for VTE, patients with filters had higher mortality rate — a finding which may represent unidentified comorbidities given the limitations of the observational nature of this study.

These studies have placed an emphasis on the retrievable filter concept, in which the embolic risk appears to be highest early on, while the thrombotic complications, including recurrent DVT and caval thrombosis, appear later. This controversy has caused much confusion in the medical community, as many physicians feel that lifelong anticoagulation may be necessary in any patient with an IVC filter. A 2008 meta-analysis finds a non–statistically significant trend toward decreased VTE rates in patients undergoing postfilter anticoagulation, suggesting that patients without anticoagulation are not at dramatically increased risk. Additionally, another group of researchers published results from a prospective registry of filter patients in Michigan showing a similar rate of IVC occlusion and recurrent DVT in patients with filters regardless of the use of anticoagulation. This suggests that patients with permanent filters may not require indefinite anticoagulation after completion of an appropriate duration of anticoagulant therapy for the thromboembolic event that prompted filter insertion.

Risks and Complications

Filter designs as well as indications continue to evolve. No ideal filter exists. Although filters are effective at reducing the incidence of PE, there is a

3% to 5% PE recurrence rate. In a 26-year single-institution study of 1,765 filters, rates of major complication associated with placement were 0.3%, and postinsertion migration, fracture, and caval perforation ranged from 0.1% to 0.2%. The rate of caval thrombosis was 2.7% (3.2% if the Mobin-Uddin device is included). Other authors cite a 2% to 10% caval thrombosis rate, and up to 30% may thrombose over the long term. Another study shows 4% to 11% complication rates after filter insertion and death in 0.12% of these patients. As above, filters appear to increase the incidence of recurrent DVT and have not been shown to increase overall survival in the long term. Cross-sectional imaging findings of complications such as maldeployment, malpositioning, tilt, migration, perforation, fragmentation, caval thrombosis, and recurrent PE are described.

A 2010 article evaluating the Bard Recovery and G2 filters demonstrated alarmingly high rates of strut fractures and complications. In this retrospective, single-center, cross-sectional study, it was found that the Bard Recovery had a 25% strut fracture rate (7 out of 28) with 71% fragment embolization to the heart. The Bard G2 was found to have a 12% strut fracture rate (6 out of 52), with two of the six patients having asymptomatic end-organ embolization. In total, a 16% strut fracture was noted for the Bard filters. This prompted an FDA warning on 8/9/2010: "Since 2005, the FDA has received 921 device adverse event reports involving IVC filters, of which 328 involved device migration, 146 involved embolizations (detachment of device components), 70 involved perforation of the IVC, and 56 involved filter fracture." It goes on to recommend that "implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed." It stops short of any direct recommendations against use of filters or their indications, although the need for additional research is indicated.

The only definitive indications for vena cava filter placement are as described in the American College of Chest Physicians (ACCP) Conference on Antithrombotic and Thrombolytic Therapy guidelines, including the contraindication to, complications from, and failure of anticoagulation. Large, rigorously designed randomized, controlled trials lasting 2 years or more in patients with these indications are required. Anticoagulation should be compared to use of permanent and retrievable filters. Outcomes should include rates of PE and DVT, filter-related complications, mortality, and post-thrombotic syndrome. These recommendations are also echoed in a 2009 consensus statement.

Filter Retrieval

The successful removal of retrievable filters requires diligent patient follow-up and interdepartmental cooperation, and even so, successful removal is not always possible. The many unanswered questions and further study directions regarding retrievable filters are delineated by a group of researchers, including timing of removal, management of trapped thrombus at the time of removal, effectiveness in reducing PE, and whether filter removal prevents caval thrombosis. Vigilance on the part of the implanting physician is needed to work with referring physicians to improve rates of patient follow-up for retrieval of the filters when indicated. Multiple studies are published that highlight the poor retrieval rates of IVC filters, despite good follow-up for some populations such as military patients. Additional studies that focus on algorithms to improve retrieval rates have been published, including one study that demonstrated that a dedicated IVC filter clinic resulted in improving retrieval rates from 29% preclinic to 60% postclinic. Similar significantly improved retrieval rates are reported by another study that reports an improvement from 42% to 95% retrieval of the eligible patients following implementation of a retrieval algorithm, with the help of the trauma service in their institution.

Retrieval procedures have also evolved over the course of the last 10 years, including the use of multiple new snares from various companies, and more aggressive techniques such as the use of lasers for embedded filters.

Summary

- VTE remains an important cause of patient morbidity and mortality. The primary therapy for VTE is pharmacological. In clinical situations where patients with VTE cannot be treated with anticoagulation, IVC filters remain a safe and effective method to prevent fatal PE.
- The clinical application of IVC filters has greatly expanded in the past 20 years. Despite this fact, the limited number of prospective randomized trials of IVC filter patient populations is recognized as a problem when making recommendations about the clinical use of IVC filters. Patients with absolute indications, such as those with VTE and contraindication or complication of anticoagulation, have the highest consensus use for IVC filters. Patients with relative indications for IVC filter insertion may have lower consensus ratings, while prophylactic use of filters such as in trauma populations is still a debated and controversial subject with wide practice variation. The multidisciplinary consensus statement published in the Journal of Vascular and Interventional Radiology in 2009 and other meta-analysis studies highlight the need for funding and research in use of prophylactic filters in trauma patients.
- For the present, the indications for use of permanent and retrievable IVC filters remain unchanged. Future studies may identify subpopulations of patients with specific clinical indications that may warrant the use of retrievable IVC filters. The present use of retrievable filters is limited in many instances by the small number of filters that are actually removed. Institution-implemented algorithms and more focused attention on IVC filter retrieval such as dedicated clinics have been shown to improve retrieval rates. In view of the recent articles demonstrating higher filter fracture rates than previously realized, other filter complications, and the most recent FDA warning on filters, it is imperative to focus resources on improving retrieval rates.
- Symptomatic chronic PE patients should be treated with pharmacologic methods and IVC filtration and referred to specialized centers to determine whether pulmonary thromboendarterectomy is appropriate for them.

- SVC filter use continues to increase but is currently considered off-label use, as no current-generation IVC filters are specifically designed or approved for this location.
- While IVC filter complication rates are low, severe complications do occasionally occur. Future research should better define the risk/benefit ratio of IVC filtration for various patient populations.

Abbreviations

- CT, computed tomography
- IVC, inferior vena cava
- KUB, kidney, ureter, and bladder X-ray
- SVC, superior vena cava
- US, ultrasound

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Venous thromboembolism (VTE), including pulmonary embolus (PE) and deep venous thrombosis (DVT)

Guideline Category

Assessment of Therapeutic Effectiveness

Management

Prevention

Treatment

Clinical Specialty

Cardiology

Family Practice

Hematology

Internal Medicine

Radiology

Surgery

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of inferior vena cava (IVC) filter placement and retrieval for prevention and treatment of venous thromboembolism

Target Population

Patients diagnosed with or at risk for venous thromboembolism

Interventions and Practices Considered

1. Inferior vena cava (IVC) filter (permanent or retrievable)
2. Anticoagulation
3. Observation/conservative management
4. Pulmonary thromboendarterectomy
5. Intermittent pneumatic compression devices
6. Surveillance ultrasound (US)
7. Superior vena cava (SVC) filter (permanent or retrievable)
8. Endovascular therapy
9. Retrieval of IVC filters
    - Retrieval of a filter placed for prophylaxis
    - Retrieval of a filter placed for deep-vein thrombosis/pulmonary embolism
    - Considerations for failed first retrieval attempts, including permanent filters

Major Outcomes Considered

- Incidence of pulmonary embolus (PE)
- Incidence of deep venous thrombosis (DVT)
- Mortality

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis, and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Modified Delphi Technique

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three rating rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of inferior vena cava (IVC) filter placement and other interventions for the prevention and treatment of venous thromboembolism

Potential Harms

Major Complications of Anticoagulation

Major bleeding is the most significant complication of anticoagulation. It is defined as intracranial or retroperitoneal bleeding or bleeding that requires hospitalization or transfusion while the patient is on therapeutic levels of anticoagulants. When anticoagulation therapy for venous thromboembolism (VTE) must be stopped because of major bleeding, placement of an inferior vena cava (IVC) filter should be considered. Heparin-induced thrombocytopenia — defined as platelet count below 50,000/µL, with or without arterial thrombosis — is also considered to be a complication, and placement of an IVC filter should be considered after heparin is discontinued.

Risks and Complications of Inferior Vena Cava Filter

Although filters are effective at reducing the incidence of pulmonary embolism (PE), there is a 3% to 5% PE recurrence rate. In a 26-year single-institution study of 1,765 filters, rates of major complication associated with placement were 0.3% and postinsertion migration, fracture, and caval perforation ranged from 0.1% to 0.2%. The rate of caval thrombosis was 2.7% (3.2% if the Mobin-Uddin device is included). Other authors cite a 2% to 10% caval thrombosis rate, and up to 30% may thrombose over the long term. Another study shows 4% to 11% complication rates after filter insertion and death in 0.12% of these patients. Filters appear to increase incidence of recurrent deep venous thrombosis (DVT) and have not been shown to increase overall survival in the long term. Cross-sectional imaging findings of complications such as maldeployment, malpositioning, tilt, migration, perforation, fragmentation, caval thrombosis, and recurrent PE have been described.

A 2010 article evaluating the Bard Recovery and G2 filters demonstrated alarmingly high rates of strut fractures and complications. In this retrospective, single-center, cross-sectional study, it was found that the Bard Recovery had a 25% strut fracture rate (7 out of 28) with 71% fragment embolization to the heart. The Bard G2 was found to have a 12% strut fracture rate (6 out of 52), with two of the six patients having asymptomatic end-organ embolization. In total, a 16% strut fracture was noted for the Bard filters. This prompted a U.S. Food and Drug Administration (FDA) warning on 8/9/2010: "Since 2005, the FDA has received 921 device adverse event reports involving IVC filters, of which 328 involved device migration, 146 involved embolizations (detachment of device components), 70 involved perforation of the IVC, and 56 involved filter fracture." It goes on to recommend that "implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from PE is no longer needed." It stops short of any direct recommendations against use of filters or their indications, although the need for additional research is indicated.

Contraindications

Contraindications

- Absolute contraindications to anticoagulation include unsecured intracranial aneurysm after subarachnoid hemorrhage, acute intracerebral hemorrhage, or hematomyelia and current or recent major gastrointestinal hemorrhage or lesions at high risk of bleeding (e.g., esophageal varices). Relative contraindications include recent (within two weeks) major surgery, major trauma including cardiopulmonary resuscitation (CPR) or deep biopsy, uncontrolled hypertension, renal or hepatic disease, current guaiac-positive stools, and known bleeding diatheses.
- Warfarin is contraindicated for anticoagulation in pregnancy due to teratogenicity.
- Cancer has been considered a contraindication to inferior vena cava (IVC) filters in some instances.

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA)

have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Kinney TB, Aryafar H, Ray CE Jr, Lorenz JM, Burke CT, Darcy MD, Fidelman N, Gervais DA, Hohenwalter EJ, Kapoor BS, Kolbeck KJ, Kouri BE, Mansour MA, Nair AV, Rochon PJ, Shaw CM, Expert Panel on Interventional Radiology. ACR Appropriateness CriteriaÂ® radiologic management of inferior vena cava filters. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 10 p. [69 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1996 (revised 2012)

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

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Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Interventional Radiology

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Kinney TB, Panko JE, Funaki BS, Ray CE Jr, Brown DB, Gemery JM, Kostelic JK, Lorenz JM, Mansour MA, Millward SF, Nemcek AA Jr, Owens CA, Reinhart RD, Silberzweig JE, Vatakencherry G, Expert Panel on Interventional Radiology. ACR Appropriateness Criteria® radiologic management of inferior vena cava filters. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 8 p.

Guideline Availability

Electronic copies: Available from the American College of Radiology (ACR) Web site .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – therapeutic studies. Reston (VA): American College of Radiology; 2013 Nov. 4 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria® radiologic management of inferior vena cava filters. Evidence table. Reston (VA): American College of Radiology; 2012. 18 p. Electronic copies: Available from the ACR Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on May 12, 2010. This summary was updated by ECRI Institute on July 27, 2010 following the FDA drug safety communication on Heparin. This summary was updated by ECRI Institute on April 17, 2013. This summary was updated by ECRI Institute on March 10, 2014 following the U.S. Food and Drug Administration advisory on Low Molecular Weight Heparins.

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